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Notice to Health Care Providers:

FDA Issues Additional Patient Notification on New England Compounding Center Products

On October 15, 2012, the Food and Drug Administration issued a new statement on the ongoing outbreak of infections associated with the injection of products produced and distributed by the New England Compounding Center (NECC). The full statement is available at the following link: http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm

FDA has reported a patient with possible meningitis potentially associated with epidural injection of an additional NECC product, triamcinolone acetonide. The cases of meningitis and other infections identified to date have been associated with a similar type of steroid, methylprednisolone acetate.

In addition, there has been one report of a transplant patient with *Aspergillus fumigatus* infection who received NECC cardioplegic solution during surgery. The investigation of this patient's case is ongoing and there may be other explanations for this infection.

The FDA had previously issued guidance for medical professionals that all products by NECC should be retained, secured and withheld from use. Based on the new information and an abundance of concern regarding the sterility of any NECC injectable drugs, FDA advises you to follow-up with patients who received any injectable product, including ophthalmic drugs, or cardioplegia solutions purchased from or produced by NECC on or after May 21, 2012. At this time, no cases of infection have been reported in connection with any NECC produced ophthalmic drug that is injectable or used in conjunction with eye surgery, but FDA believes this class of products could present potentially similar risks of infection. The FDA does not currently urge follow-up of patients who were treated with topical NECC products, including lotions, creams or eye drops not used during surgery and suppositories.

The Massachusetts Department of Public Health (CDC) continues to collaborate with the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) on this multi-state investigation. DPH will support the FDA effort through outreach to Massachusetts facilities who received the additional medications from NECC.

Please contact the DPH Epidemiology hotline at 617-983-6800 to report suspect or confirmed infections presumed to be related specifically to the injection of an NECC product.

Clinicians are also requested to report any suspected adverse events following use of these products to FDA's MedWatch program at 1-800-332-1088 or www.fda.gov/medwatch

October 17, 2012